Reference number(s)
1615-A

Specialty Guideline Management

DARZALEX (daratumumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Darzalex is indicated for the treatment of adult patients with multiple myeloma:
1. in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy.
2. in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant.
3. in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant.
4. in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy.
5. in combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.
6. as monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

B. Compendial Uses
1. Therapy for previously treated multiple myeloma for relapsed or progressive disease in combination with carfilzomib and dexamethasone
2. Treatment for relapsed/refractory systemic light chain amyloidosis

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Multiple Myeloma
Authorization of 12 months may be granted for the treatment of multiple myeloma when any of the following criteria is met:
1. The requested medication will be used in combination with lenalidomide and dexamethasone and either of the following criteria is met:
   i. The member is not a candidate for autologous stem cell transplant and the regimen will be used as primary therapy
   ii. The member has received one or more prior therapies
2. The requested medication will be used in combination with bortezomib, melphalan, and prednisone as primary therapy in members who are not a candidate for autologous stem cell transplant.

3. The requested medication (for a maximum of 16 doses) will be used in combination with bortezomib, thalidomide, and dexamethasone as primary therapy in members who are eligible for autologous stem cell transplant.
4. The requested medication will be used in combination with bortezomib and dexamethasone in members who have received at least one prior therapy.
5. The requested medication will be used in combination with carfilzomib and dexamethasone when the member has relapsed or progressive disease.
6. The requested medication will be used in combination with pomalidomide and dexamethasone in members who have received at least two prior therapies including a proteasome inhibitor (PI) and an immunomodulatory agent.
7. The requested medication will be used as a single agent in members who have received at least three prior therapies, including a PI and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent

B. Systemic Light Chain Amyloidosis
Authorization of 12 months may be granted for the treatment of systemic light chain amyloidosis when the member has relapsed or refractory disease.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when either of the following regimen or indication-specific criteria is met:

A. All members (including new members) requesting the requested medication in combination with bortezomib, thalidomide, and dexamethasone for multiple myeloma must meet all initial criteria.
B. For all other regimens and indications listed in Section II, there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Darzalex [package insert]. Horsham, PA: Janssen Biotech Inc; September 2019.
2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 13, 2020.
3. The NCCN Clinical Practice Guidelines in Oncology Multiple Myeloma (Version 1.2020) 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 01, 2019.